

Allograft for Fusion


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Comparator or Reference = Allograft

Standard of Care = Allograft

Evidence = Allograft

Practicality = Allograft

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Reference

FDA choses allograft
Just in Cervical Disc Literature



Int J Spine Surg 2014; 8: 7
Published online 2014 Dec 1, doi: 10.1006/ijss.2014.0007

Multi-center, Prospective, Randomized, Controlled Investigational Device Exemption Clinical Trial Comparing Mobi-C Cervical Artificial Disc to Anterior Discectomy and Fusion in the Treatment of Symptomatic Degenerative Disc Disease in the Cervical Spine

Michael S. Hasey, MD, MD, Hsu W. Bao, MD, Robert Davis, MD, Steven Geisler, MD, Greg Hoffman, MD, Kim Kim, MD, Francis D. Nelder, MD, Daniel Patsorn, MD, Rajiv Rashid, MD, and John Stokes, MD

sc versus anterior
nulticenter

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Evidence

Level 1 Data supporting the use of allograft
Numerous prospective studies demonstrating efficacy and safety
600 patients
Cervical fusion rates
90-97 percent

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DBMs

Table with 7 columns: Company, DBM Use, Study Design, Diagnosis / Prevalence, Application Technique and Graft Composite, Results (Main Outcome(s)), Reference (Original article, reference list below), and S1. It contains three rows of data regarding various DBM studies.

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Enhanced Cellular Allografts

- Osteocell
- Trinity
- Vivogen
- Bio-4
- Cellentra




Practicality

- Osteoconductive at minimum
- Most cost efficient
- Evidence proves use as stand alone and graft extender
- Mildly osteoinductive
- Best Safety Profile



Future Allogenic Cells



Allogeneic Mesenchymal Precursor Cells Off the shelf solution

- Homogeneous cell population, STRO-1 positive
- Well-controlled, efficient large-scale cell expansion
- Batch-to-batch consistency
- Stringent release criteria
- Regulated as a biological product and supported with clinical studies conducted under FDA's IND regulations

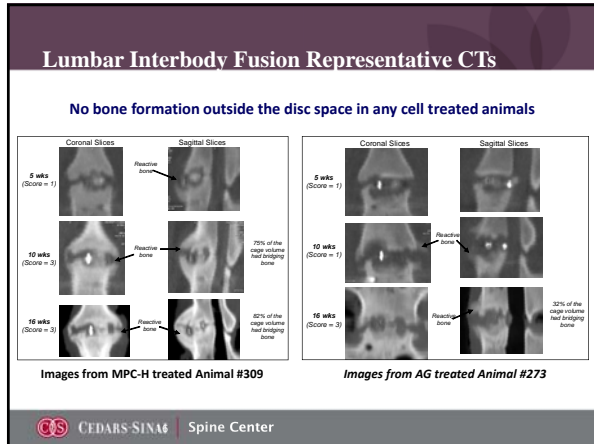
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Bioreactor Cell Processing

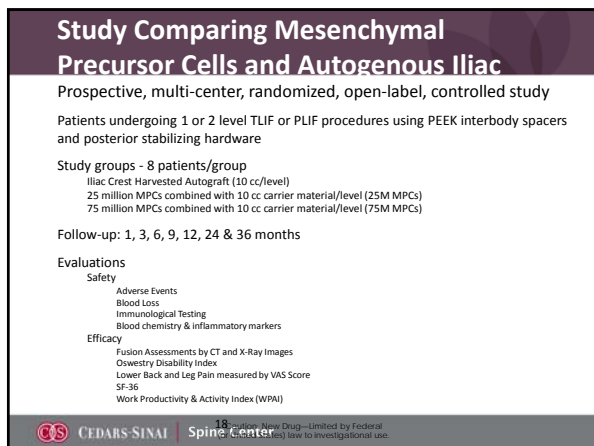
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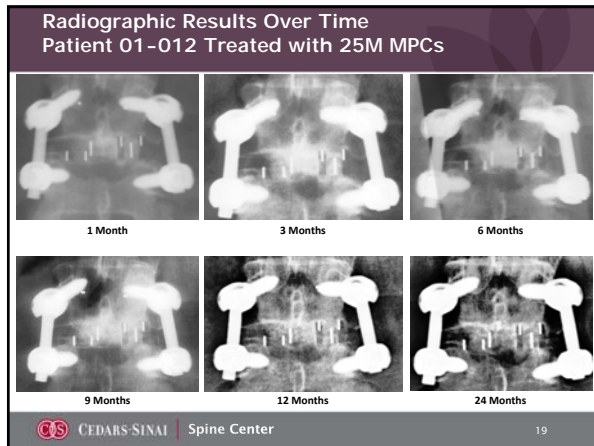
Commercial Viability

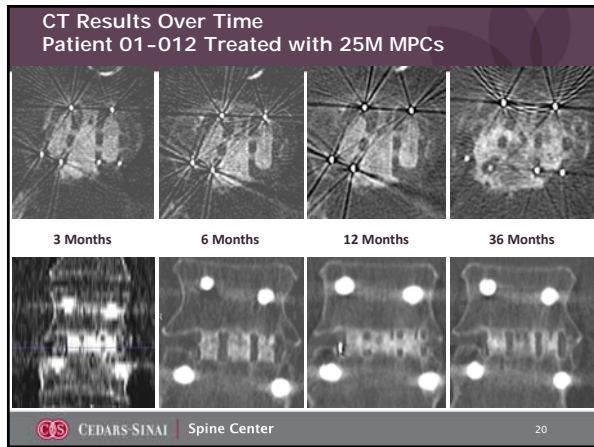
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- Not only Gold Standard Now

- But also Gold Standard for the future.

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